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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,923	09/15/2003	Peter M. Bonutti	2500DV2CN2DV3CN2	2728

7590 06/22/2006

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ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/22/2006

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/662,923
Filing Date: September 15, 2003
Appellant(s): BONUTTI, PETER M.

Dana A. Brussel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 17, 2006 appealing from the Office action mailed August 3, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings (other than the related appeal for Application Serial Number 10/743,192 cited by appellant) which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,655,746	DANIELS ET AL.	4-1987
5,180,367	KONTOS ET AL.	1-1993
4,981,478	EVARD ET AL.	1-1991
4,690,140	MECCA	9-1987

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 2, 5, 7-9 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367). Daniels et al. disclose first tubular member 68 having an open proximal end, first inflatable member 72, second tubular member 16 having an open proximal end and an open distal end defining a bore 18 therethrough (col. 3, lines 18-22) and second inflatable member 30. Daniels et al. fail to disclose the first inflatable member 72 and first tubular member 68 having an open distal end (since guidewire 74 plugs the distal end of the first inflatable member 72 as indicated in col. 4, lines 54-59). However, Kontos et al. teach that the tubular member of the inner, pilot balloon can

have an open distal end so that it can slidably receive the guidewire instead of being fixed to the guidewire (col. 8, lines 8-19). This arrangement has the self-evident advantage of enabling the position of the tubular member to be adjusted relative to the guidewire. One of the advantages of having a catheter slidable on a guidewire as opposed to being fixed to the guidewire is as follows: It is often a time consuming process to insert a guidewire through the various branches of the vasculature to reach the target site. If, after the guidewire and catheter (which is slidable on the guidewire) have been inserted into the body, it is determined that a different catheter (e.g. one with a different sized balloon) is needed, the guidewire may remain in the body while the catheter is replaced. The insertion of the second catheter over the guidewire is relatively quick and easy because the path to the target site has already be made and is maintained by the pre-inserted guidewire. However, if the guidewire is fixed to the catheter and the entire assembly has to be replaced, when the second catheter (with a different sized balloon) and guidewire is inserted into the body, the time consuming process of inserting the guidewire has to be repeated since the path to the target site has been lost when the first guidewire was removed from the body. It would have been obvious to make the distal

end of the first inflatable member 72 and first tubular member 68 of Daniels et al. et al. open so that they can slidably receive a guidewire so that it too would have this advantage. The slidable guidewire is considered to be the surgical instrument referred to in the claim. Movement of the first inflatable member 72 towards the second inflatable member 30 is inherently capable of capturing body tissue therebetween, particularly since the second inflatable member 30 can be as large as 4 cm in diameter as indicated in col. 3, lines 55-59 and since the first inflatable member 72 appears to have a diameter which is comparable to the diameter of the second inflatable member 30 as seen in figure 6.

Claims 3 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Evard et al. (4,981,478). Daniels et al. fail to disclose an inner member defining an annular space with the first tubular member. However, Evard et al. teach that a balloon catheter can be constructed with an inner tubular member 13 and outer tubular member 11 with an annular space therebetween (col. 4, lines 19-30). This arrangement has the advantage of enabling inflation fluid to pass through the annular space and a guidewire to slidably pass through the inner

tubular member while maintaining a small profile. It would have been obvious to so construct the Daniels et al. first tubular member so that it too would have this advantage.

Claims 11 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Mecca (4,690,140). The distal end of first tubular member 68 of Daniels et al., as modified above to be open so that it can slidably receive a guidewire (the claimed surgical instrument) would inherently be capable of receiving an endoscope or laparoscopic instrument since an endoscope or laparoscopic instrument can be as small in diameter as a guidewire. Mecca is cited to support this assertion since it discloses a very thin endoscopic guide member 1 which is broadly an endoscope since it allows viewing into the area (col. 2, lines 10-14 and col. 6, lines 1-9). Note that the surgical instrument itself is not part of the claimed combination.

(10) Response to Argument

Appellant alleges on page 8 of the brief that modifying the inner balloon of Daniels to have an open distal end would result in the balloon being incapable of retaining pressurized fluid and thus render the device inoperable for its intended purpose. This allegation is incorrect for the following reasons:

Making the distal end of the balloon 72 of Daniels et al. open to slidably receive a guidewire as taught by Kontos et al. in col. 8, lines 8-19 would not prevent the balloon from retaining pressurized fluid since the balloon itself would be sealed while the guidewire lumen passing through the balloon would have an open distal end. Note that Kontos et al. teach using a dual lumen pilot catheter (col. 8, lines 10-11) for the alternative procedure wherein the catheter is slidable on the guidewire described in col. 8, lines 8-19. In such a dual lumen catheter (shown in figure 9 of Kontos et al. for balloon 34, for example), one lumen is a guidewire lumen passing through the balloon and one lumen is an inflation lumen in communication with the interior of the balloon wherein fluid is prevented from escaping from the balloon out the guidewire lumen. Therefore, the proposed modification of the Daniels et al. catheter would not result in the escape of inflation fluid from balloon 72 and thus would not render the device inoperable for its stated purpose. Further, the allegation that the proposed modification of Daniels would necessitate the removal of the flexible spring 76 is incorrect. Flexible spring 76 would still be retained and attached to the guidewire (but not the catheter) just as flexible spring 80 of Kontos et al. is attached to the guidewire

78, but not the catheter, as described in col. 8, lines 13-19 of Kontos et al.

Appellant alleges on page 8 of the brief that modifying the inner balloon of Daniels to have an open distal end would result in the balloon not rotating when the guidewire is rotated and thus render the device inoperable for its intended purpose. This allegation is incorrect for the following reasons:

The proposed modification of the Daniels et al. device in view of Kontos et al. would not render the Daniels et al. device incapable of being maneuvered from the proximal end of the device since a steerable guidewire could be first inserted into the body to the intended location and the balloon catheter inserted over it and guided (i.e. maneuvered) to the same location as described in col. 8, lines 8-19 of Kontos et al. Alternatively, the guidewire and catheter could be inserted as a unit as described in col. 8, lines 15-19 of Kontos et al. In either method, although rotation of the guidewire would not result in rotation of the balloon, the rotation of the balloon is not necessary for the guiding of the assembly. A guidewire functions to navigate through the various branches of the vasculature as follows: When the guidewire is inserted into the main trunk of a blood vessel and distal end of the guidewire reaches the intersection of the main trunk with a side branch of

the vessel (wherein the side branch is intended to be the future path of the guidewire), the guidewire is rotated until its curved distal end (shown in figures 9 and 10 of Kontos et al. for example) is pointed toward the side branch. The guidewire is then pushed forward and passes into the side branch since it is pointed in that direction. This process is repeated several times until the guidewire reaches its target location. It is the rotation of the guidewire to the desired orientation which is important in the guiding function since it is the guidewire which has the curved distal end (sometimes referred to as a J-shape) which directs the guidewire to a particular direction. However, the rotation of the surrounding catheter (if there is one) plays no part at all in the guiding function. Thus, rotation of the balloon is not necessary for the guiding of the assembly into the body.

Appellant alleges on pages 10-11 of the brief that Daniels fail to disclose that either of the balloons should be moved when in the inflated state. In response, it is submitted that claim 13 is an apparatus claim and not a method claim. Either of the Daniels balloons is clearly inherently capable of being moved when in the inflated state. For example, if the Daniels apparatus in placed in tissue similar to the tissue shown in figure 13 of appellant's specification, the Daniels balloons can

be first inflated and then one balloon can be moved toward the other balloon to separate tissue. Nothing about the Daniels structure prevents such a use.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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